

We Claim:

5 1. A method of detecting the presence of a target BS274 polynucleotide in a test sample, said method comprising:

- 10 (a) contacting the test sample with at least one BS274-specific polynucleotide or complement thereof, wherein said BS274-specific polynucleotide has at least 50% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NOS 1-7, and fragments or complements thereof; and
- (b) detecting the presence of target BS274 polynucleotides from the test sample which bind to said BS274-specific polynucleotide.

15 2. The method of claim 1, wherein said target BS274 polynucleotide is attached to a solid phase prior to performing step (a).

3. The method of claim 1, wherein said BS274-specific polynucleotide is attached to a solid phase prior to performing step (a).

20 4. A method for detecting BS274 mRNA in a test sample, said method comprising:

- (a) performing reverse transcription on said sample using at least one primer in order to produce cDNA;
- (b) amplifying the cDNA obtained from step (a) using BS274 oligonucleotides as sense and antisense primers to obtain BS274 amplicon; and
- 25 (c) detecting the presence of said BS274 amplicon, wherein the BS274 oligonucleotides utilized in steps (a) and (b) have at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NOS 1-7, and fragments or complements thereof.

30 5. The method of claim 4, wherein said test sample is reacted with a solid phase prior to performing one of steps (a), (b), or (c).

6. The method of claim 4, wherein said detection step comprises utilizing a detectable label capable of generating a measurable signal.

35 7. A method of detecting a target BS274 polynucleotide in a test sample suspected of containing said target polynucleotide, comprising:

- Sub B3
concl 7
5
- (a) contacting the test sample with at least one BS274 oligonucleotide as a sense primer and with at least one BS274 oligonucleotide as an anti-sense primer and amplifying to obtain a first stage reaction product;
- (b) contacting said first stage reaction product with at least one other BS274 oligonucleotide to obtain a second stage reaction product, with the proviso that the other BS274 oligonucleotide is located 3' to the BS274 oligonucleotides utilized in step (a) and is complementary to said first stage reaction product; and
- (c) detecting said second stage reaction product as an indication of the presence of the target BS274 polynucleotide, wherein the BS274 oligonucleotides utilized in steps (a) and (b) have at least 50% identity with a sequence selected from the group consisting SEQUENCE ID NOS 1-7, and fragments or complements thereof.

8. The method of claim 7, wherein said test sample is reacted with a solid phase prior to performing one of steps (a), (b), or (c).

9. The method of claim 7, wherein said detection step comprises utilizing a detectable label capable of generating a measurable signal.

10. The method of claim 9, wherein said detectable label is reacted to a solid phase.

Sub B3
BA

11. A test kit useful for detecting BS274 polynucleotide in a test sample, said test kit comprising a container containing at least one BS274 polynucleotide, having at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NOS 1-7, and fragments or complements thereof.

12. A purified polynucleotide derived from a BS274 nucleic acid molecule, wherein said polynucleotide has at least 50% identity with a sequence selected from the group consisting of (a) SEQUENCE ID NOS 1-3, 6, 7; (b) fragments of SEQUENCE ID NOS 1-5; and (c) complements of (a) or (b).

13. The polynucleotide of claim 12, wherein said polynucleotide hybridizes selectively to a BS274 nucleic acid sequence.

14. The polynucleotide of claim 12, wherein said polynucleotide has an overall length of about 20 to about 50 nucleotides.

15. The polynucleotide of claim 12, wherein said polynucleotide has an overall length of about 10 to about 25 nucleotides.

5 16. The polynucleotide of claim 12, wherein said polynucleotide is produced by recombinant techniques.

17. The polynucleotide of claim 12, wherein said polynucleotide is produced by synthetic techniques.

10

18. The polynucleotide of claim 12, wherein said polynucleotide comprises a sequence encoding at least one BS274 epitope.

15

19. The polynucleotide of claim 12, wherein said polynucleotide is attached to a solid phase.

20. The polynucleotide of claim 19, wherein said solid phase comprises an array of polynucleotide molecules attached thereto.

20

21. A recombinant expression system comprising a nucleic acid sequence that includes an open reading frame derived from a BS274 polynucleotide, wherein said open reading frame is operably linked to a control sequence compatible with a desired host, and said nucleic acid sequence has at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NOS 1-7, and fragments or complements thereof.

25

22. A cell transfected with the recombinant expression system of claim 21.

30 23. A BS274 polypeptide having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 17, SEQUENCE ID NO 18, SEQUENCE ID NO 19, SEQUENCE ID NO 20, SEQUENCE ID NO 21, and fragments thereof.

35 24. The polypeptide of claim 23, wherein said polypeptide is produced by recombinant techniques.

25. The polypeptide of claim 23, wherein said polypeptide is produced by synthetic techniques.

26. A specific binding molecule which binds to at least one BS274 epitope,
5 wherein said BS274 epitope is derived from an amino acid sequence having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 17, SEQUENCE ID NO 18, SEQUENCE ID NO 19, SEQUENCE ID NO 20, SEQUENCE ID NO 21, and fragments thereof.

10 27. The specific binding molecule of claim 26, wherein said molecule is an antibody molecule.

28. A test kit for determining the presence of BS274 antigen or anti-BS274
15 antibody in a test sample, said kit comprising a container containing a BS274 polypeptide having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 17, SEQUENCE ID NO 18, SEQUENCE ID NO 19, SEQUENCE ID NO 20, SEQUENCE ID NO 21, and fragments thereof.

29. The test kit of claim 28, wherein said BS274 polypeptide is attached to a
20 solid phase.

30. A test kit for determining the presence of BS274 antigen in a test
sample, said kit comprising a container containing a specific binding molecule which binds to a BS274 antigen having at least one BS274 epitope.

25 31. The kit of claim 30, wherein said specific binding molecule is attached to a solid phase.

32. A method for producing a polypeptide comprising at least one BS274
30 epitope, said method comprising incubating host cells that have been transfected with an expression vector containing a polynucleotide sequence encoding a polypeptide, wherein said polypeptide comprises an amino acid sequence having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 17, SEQUENCE ID NO 18, SEQUENCE ID NO 19,
35 SEQUENCE ID NO 20, SEQUENCE ID NO 21, and fragments thereof.

33. A method for detecting BS274 antigen in a test sample suspected of containing said BS274 antigen, comprising:

- (a) contacting the test sample with a specific binding molecule which binds to at least one epitope of a BS274 antigen selected from the group consisting of
5 SEQUENCE ID NO 17, SEQUENCE ID NO 18, SEQUENCE ID NO 19,
SEQUENCE ID NO 20, SEQUENCE ID NO 21, and fragments thereof, wherein said contacting is performed for a time and under conditions sufficient for the formation of binding molecule/antigen complexes; and
(b) detecting the presence of said complexes as an indication of the presence
10 of said BS274 antigen.

34. The method of claim 33, wherein said specific binding molecule is an antibody molecule or a fragment thereof.

- 15 35. The method of claim 33, wherein said specific binding molecule is attached to a solid phase.

36. A method for detecting the presence of antibodies specific for a BS274 antigen in a test sample suspected of containing such antibodies, said method
20 comprising:

- (a) contacting the test sample with a BS274 polypeptide, wherein said BS274 polypeptide contains at least one BS274 epitope derived from an amino acid sequence having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 17, SEQUENCE ID NO 18, SEQUENCE ID
25 NO 19, SEQUENCE ID NO 20, SEQUENCE ID NO 21, and fragments thereof, and further wherein said contacting is performed for a time and under conditions sufficient to allow antigen/antibody complexes to form; and
(b) detecting the presence of said complexes as an indication of the presence of antibodies specific for a BS274 antigen.

- 30 37. The method of claim 36, wherein said BS274 polypeptide is attached to a solid phase.

38. A cell transfected with a nucleic acid sequence encoding at least one BS274 epitope, wherein said nucleic acid sequence is selected from the group consisting of SEQUENCE ID NOS 1-7, and fragments or complements thereof.

39. A method for producing antibodies which specifically bind to BS274 antigen, comprising administering to an individual an isolated immunogenic polypeptide or fragment thereof in an amount sufficient to elicit an immune response, wherein said immunogenic polypeptide comprises at least one BS274 epitope and has at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NO 17, SEQUENCE ID NO 18, SEQUENCE ID NO 19, SEQUENCE ID NO 20, SEQUENCE ID NO 21, and fragments thereof.

40. A method for producing antibodies which specifically bind to BS274 antigen, comprising administering to an individual a plasmid comprising a sequence which encodes at least one BS274 epitope derived from a polypeptide having an amino acid sequence selected from the group consisting of SEQUENCE ID NO 17, SEQUENCE ID NO 18, SEQUENCE ID NO 19, SEQUENCE ID NO 20, SEQUENCE ID NO 21, and fragments thereof.

41. The test kit of claim 11 further comprising a container with tools useful for collection of said sample, wherein the tools are selected from the group consisting of lancets, absorbent paper, cloth, swabs and cups.

42. The test kit of claim 28 further comprising a container with tools useful for collection of said sample, wherein the tools are selected from the group consisting of lancets, absorbent paper, cloth, swabs and cups.

43. The test kit of claim 30 further comprising a container with tools useful for collection of said sample, wherein the tools are selected from the group consisting of lancets, absorbent paper, cloth, swabs and cups.

44. The test kit of claim 30, wherein said specific binding molecule is an antibody or fragment thereof.

45. The polynucleotide of claim 12, wherein said polynucleotide codes for a BS274 protein which comprises an amino acid sequence having at least 50% identity to SEQUENCE ID NO 17.

46. The polynucleotide of claim 12, wherein said polynucleotide comprises DNA having at least 50% identity with SEQUENCE ID NO 6 or SEQUENCE ID NO 7.

Sub
B35

47. The method of claim 1, wherein the presence of said target BS274 polynucleotide in the test sample is indicative of breast disease.

48. The method of claim 4, wherein the presence of said amplicon is indicative of breast disease.

49. The method of claim 7, wherein the presence of said second stage reaction product is indicative of breast disease.

50. The method of claim 33, wherein detection of said complexes is indicative of breast disease.

51. The method of claim 36, wherein detection of said complexes is indicative of breast disease.